

DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration 158-15 Liberty Avenue Jamaica, NY 11433

March 5, 2002

WARNING LETTER

Ref: NYK-2002-26

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Filippe Ramos President La Vaquita Cheese Corp. 304 East 110th Street New York, NY 10029

Dear Mr. Ramos:

We inspected your firm, located at 304 East 110th Street, on January 15, 2002. During the inspection, physical samples and labeling for your product, "Queso Fresco Fresh Cheese" were collected. Review of the labeling for this product found a serious violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations Part 101 - Food Labeling (21 CFR Part 101).

This product is misbranded within the meaning of Section 403 (q)(1) of the Act in that the label fails to bear nutrition labeling as required by 21 CFR 101.9 and the product is not exempt from this requirement under 403 (q)(5) of the Act.

Firms with fewer than 100 employees and products fewer than 100,000 units may qualify for exemption from the nutritional labeling requirements. However, businesses are responsible for filing for exemption, on an annual basis, for each product line. A sample Small Business Food Labeling Exemption Notice has been included with this letter for your information.

The above violation concerns certain labeling requirements and is not meant to be an all-inclusive list of deficiencies of your labels. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration (FDA). You should take prompt action to correct the violation. Failure to promptly correct this violation may result in regulatory action without further notice. These include seizure and/or injunction.

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You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Compliance Officer Lillian C. Aveta, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,

Jerome G. Woyshner
District Director